

Office Action Summary	Application No. 10/677,874	Applicant(s) MALACKOWSKI ET AL.	
	Examiner John P. Leubecker	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-67 and 74-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-67 and 74-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

Response to Amendment

1. The After Final Amendment filed October 6, 2009 will be entered and upon review of the finality of the rejection of the last Office action, the finality of that action is hereby withdrawn. Claims 63-67 and 74-78 are currently pending.

2. The declaration under 37 CFR 1.132 filed October 6, 2009 is sufficient to show common ownership of this application and the Moctezuma reference (U.S. Pat. 6,306,126). Coupled with Applicant's statement that the invention was subject to assignment to the same entity at the time the invention was made (note page 6 of the remarks filed October 6, 2009), Applicant has successfully disqualified Moctezuma as a prior art reference under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chader et al. (U.S. Pat. 5,617,857) in view of Acker et al. (U.S. Pat. 6,453,190) and further in view of Schulz (U.S. Pat. 5,622,170).

As to claim 63, and referring to Figure 1, Chader et al. disclose at least two smart instruments (12,24), wherein each smart instrument includes a housing (Fig.2), a plurality of

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LEDs (20, col.6, lines 64-66) coupled to the housing, a memory circuit (36, col.9, lines 30-37) having stored information thereon related to the instrument, and a first transceiver (note interface of wires with the instrument, Fig.2), a computer system (14,16,18,28), and a sensor system (16) adapted to wirelessly sense the position of each smart instrument (col.5, lines 35-42) and to transmit position information to the computer system (col.5, lines 48-67), wherein the sensor includes a sensor array (e.g. 22) which includes a plurality of position sensors (see 22, 22, 22, Fig.1) adapted to sense position information from the LEDs (col.5, lines 38-42 and 55-65), wherein the first transceiver transmits the stored information to a second transceiver (note interface of wires with system 14) of the sensor array (col.6, lines 18-24) and the second transceiver transmits a request from the sensor system to the first transceiver to fire in a predetermined manner (col.7, lines 3-7).

Chader et al. disclose hardwired bi-directional (col.6, lines 49-56) communication adapted to transmit the information to the computer system with wires (see Fig.2) and thus fails to disclose wireless transceivers for transmitting such information (thus requiring first and second transceivers). Acker et al. discloses an analogous tracking system (note Abstract) and explicitly teaches that although the connection between the instrument and the computer uses wires, such wires can be replaced by a wireless infrared telemetry link (col.11, line 61 to col.12, line 4). Acker et al. further explicitly teaches that such use of a wireless connection avoids "the physical encumbrance of loose wires trailing from the instrument" (col.12, lines 3-4). In view of this teaching regarding a directly analogous portion of the Chader et al. reference, it would have been obvious to one of ordinary skill in the art at the time of the invention to have provided a wireless infrared connection in place of the wired connection of Chader et al. The Examiner

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takes the position that since communication is bi-directional, such infrared link must include transceivers (so that both the instrument and the system can transmit and receive the signals).

The Examiner also takes the position that the sensor array must be able to distinguish between the LEDs in order to determine their positions. Since Chader et al. fails to teach that the LEDs are all of different wavelengths or that the LED controller (44) is anything more than a circuit which controls the firing of the LEDs (col.7, lines 3-7), the Examiner believes that independent firing of the LEDs, one at a time, is inherently encompassed by Chader. However, since this is an arguable position, for completeness, the Examiner cites Schulz as evidencing that it is known in this art to independently fire the LEDs one at a time in order to distinguish them for recognition by the sensors (note time multiplexing, col.5, lines 54-60, as opposed to other ways of differentiation, col.6, lines 3-9, including pulse duration and frequency). Therefore, if not inherent, it would have been obvious to the skilled artisan to have used a differentiation technique known and used in the art in the Chader et al. system. It is noted that, upon modification to use wireless signals as discussed above, control of the LEDs by LED controller (44) would automatically be accomplished through the wireless transceivers.

As mentioned above, Chader et al. disclose that the patient tracking system (24), which can constitute a second smart instrument, can include a memory module (36, col.9, lines 30-37). Since obviousness to use a wireless connection, as taught by Acker et al., would naturally apply to the connections of all instruments, this would anticipate a patient tracking system/second instrument comprising a housing, transceiver (use of memory module and LED controller would require two-way communication) and independently fireable lights. Chader further discloses that the system is capable of, for each instrument, sending a signal identifying the instrument,

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receiving status information from the instrument (col.6, lines 49-56), and sending a request (from LED controller 44) to fire each of the lights independently (as discussed above). The Examiner takes the position that, since it would be difficult for the sensors to detect the positions of the instruments if the LEDs for each instrument were fired concurrently (especially if all markers on the instruments are the same type of LED), the LEDs are inherently fired consecutively for each consecutive instrument, meeting the limitation of the surgery system cycling successively through all smart instruments that are active. Such cycling would inherently require the LEDs on the particular instrument NOT being sensed to be set in an OFF state, meeting the limitation of temporarily setting the number of LEDs to be activated on an unused active instrument to zero.

As to claims 64-66, the computer system includes a monitor (28) which is capable of displaying an image of a patient and a representation of the used instrument (col.5, line 62 to col.6, line 2).

As to claim 67, as discussed above, cycling through the LEDs on the instruments for detecting position constitutes "alternatively" determining the position of the instruments.

5. Claims 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman (U.S. Pat. 6,675,040) in view of Shultz (U.S. Pat. 5,622,170).

As to claim 63, Cosman disclose at least two smart instruments (282 and patient tracker, not numbered in Fig.6, but analogously shown as 38 in Fig.1), wherein each smart instrument comprises a housing (note structures indicated by 38 and 60 in Fig.1, and analogously shown in Fig.6), a plurality of LEDs (note that all markers in the application can be infrared LEDs, col.3, line 58-col.4, line 3, including 314, 316 and 318 in Fig.6, which are described as light emitters,

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col.14, lines 21-26; also note 294,296 and 298, Fig.6, col.13, lines 56-59) coupled with the housing and adapted to fire independently (e.g., col., 5, lines 11-16, col.14, lines 1-4 and lines 26-27), and a first transceiver (note that transmitter 306 can both transmit and receive data, col.14, lines 8-20); a computer system (292); and a sensor system (284) adapted to wirelessly sense the position of the at least two smart instruments and to transmit position information to the computer system (col.4, lines 10-32), wherein the sensor system includes a sensor array comprising a plurality of position sensors (286,288,290) and at least a second transceiver (304, col.14,lines 8-20); and wherein, for each of the smart instruments in consecutive order, the respective second transceiver wirelessly transmits an instruction from the sensor system to the respective first transceiver thereof that causes the LEDs thereof to fire to be recognized by the surgery system (note col.16, lines 19-36 which describes tracking the various instruments consecutively or concurrently), and wherein the surgery system cycles successively through all of the smart instruments that are active and temporarily sets the number of LEDs to be activated on an unused active smart instrument to zero (consecutive tracking of each instrument, as opposed to concurrent tracking, as described in col.16, lines 19-36 using the steps as described in col.15, line 55 to col.16, line 6 would inherently suggest that the LEDs on the instrument not being tracked (unused active instrument) be set to zero). The Examiner takes the position that, although not shown or explicitly mentioned, there is reasonable evidence that the second instrument (one including LEDs 314,316,318 in Fig.6) would require a transceiver such as transmitter (306, Fig.6) since the LEDs are also synchronized in the same way as LEDs (294,296,298, col.14, lines 8-20) (note 30,32,34 on analogous instrument in Fig.1, col.5, lines 11-16).

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Although Cosman mentions that the LEDs are synchronized with shutter operation of the sensor system (col.14, lines 8-20) and flashed in a coded sequence (col.14, lines 1-4), Cosman fails to disclose any particular synchronization sequence, and thus fails to disclose that the LEDs fire independently one at a time in order. Although the Examiner takes the position that a time sequential order is just one of an finite number of obvious sequences or patterns that can be used in the design of the system to distinguish between the LEDs (Where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975)), Shultz is cited to evidence that it is known in this art to independently fire the LEDs one at a time in order to distinguish them for recognition by the sensors (note time multiplexing, col.5, lines 54-60, as opposed to other ways of differentiation, col.6, lines 3-9, including pulse duration and frequency). Therefore, if not inherent, it would have been obvious to the skilled artisan to have used a differentiation technique known and used in the art in the Cosman device.

As to claim 64-66, the computer system includes a monitor (46, Fig.1) which is capable of displaying an image of a patient and a representation of the used instrument (254, 256, 258, Fig.5).

As to claim 67, as mentioned above, note col.16, lines 19-36 as to the consecutive detection of the positions of the instruments.

6. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Messner et al. (U.S. Pat. 6,081,336) in view of Cosman (U.S. Pat. 6,675,040).

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Messner et al. disclose at least one smart instrument (35,60, Fig.1); a validation tool (50, Fig.1), the validation tool including: a base (80, Fig.4); four columns (82a,82b, Fig.3; 98a,98b, Fig.4) coupled to the base; at least one validation point (any point including 130a, Fig.4 or center of target 110, Fig.3); a plurality of infrared light emitting diodes (112a-112d, col.6, lines 39-43, col.4, lines 24-26) coupled to the base; and a computer system (30, Fig.2); a sensor system (20,55, Fig.1, col.3, line 66 to col.4, line 11, and col.4, lines 63-67) adapted to wirelessly sense the position of the at least one smart instrument and the validation tool and to transmit position information to the computer system (col.4, lines 24-28, col.5, lines 1-12), wherein the validation tool is adapted to validate the at least one smart instrument (col.5, lines 1-12); wherein the sensor system includes a sensor array (22,22); wherein the sensor system includes at least one transceiver (note that interface 55 receives information from memory 24, col.7, lines 1-13, and transmits control signals to lights source 38 and LEDs 112, col.7, lines 64-67, thus constituting a transceiver).

Messner et al. disclose that the sensor array includes two cameras (22) and thus fails to disclose that the sensor array includes at least three cameras and that they are of the linear CCD type. Cosman disclose a similar system in the same field of endeavor (note Fig.1) in which one or more cameras can comprise the sensor array (col.4, lines 10-12). The cameras can be linear infrared CCD cameras (col.13, lines 51-54). In addition, Cosman teaches that use of a third camera allows the system to verify the stereoscopic images (obtained by two cameras) and provides further accuracy or definition (col.16, lines 2-6). Since Messner et al. fails to disclose the specific type of cameras used in the sensor array, it would have been obvious to one of ordinary skill in the art to have used a type that is known in the art to be sufficient for the same

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purpose, namely linear CCD cameras, as taught by Cosman. In addition, it would have been obvious to use at least three cameras in the sensor array of Messner et al. for the beneficial reasons taught by Cosman.

7. Claims 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chader et al. (U.S. Pat. 5,617,857) in view of Acker et al. (U.S. Pat. 6,453,190) and Schulz (U.S. Pat. 5,622,170), as set forth above, and further in view of Acker et al. (U.S. Pat. 5,752,513).

As to claim 76, Chader et al. in view of Acker et al. and Shultz is described above (i.e., claim 63) with respect to the smart instrument with wireless transceiver, computer system and sensor system with wireless transceiver. Chader et al. further discloses a patient tracker (24), which constitutes a smart instrument (col.5, lines 59-62, col.9, lines 30-37) connected to the patient by what looks like a band (Fig.1) to secure the reference markers (26) with respect to the patient. Since frame (24), which includes LEDs (26), is attached to a first side (side not in direct contact with the patient) of the band-like structure, the LEDs are considered to be "on the first side" of the band-like structure. Although apparently inherent, Chader et al. fails to explicitly disclose what the band-like structure is and if it is flexible. Acker et al. ('513) discloses a similar tracking system in which the reference markers (96, col.7, lines 53-57) can be secured to the patient by a band, strap, or surgical adhesive tape (col.7, lines 57-64), all of which constitute a flexible material. Since both Chader et al. and Acker et al. teach systems in which markers are secured to the body, it would have been obvious to substitute one fastening means for another to achieve the predictable result of securing the markers to the body. The Examiner takes the position that, in view of Acker et al. ('513), it would be obvious to use the flexible band, strap or

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tape for securing the frame (24) to the patient or to merely secure the reference markers themselves (without frame 24) to the patient.

As to claim 77, it is noted that since the computer of Chader et al. can determine locations of the LEDs, determining such locations in 3D space on the flexible material, would inherently result in a contour. In addition, since Applicant's only structure for being "adapted to determine the contour of the smart instrument and perform a surface matching operation with a known contour" is a computer, the computer of Chader et al. is considered as being capable of performing such function. As to claim 78, since the flexible material can move and still be detected, it is considered a dynamic reference frame.

8. Claims 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chader et al. (U.S. Pat. 5,617,857) in view of Acker et al. (U.S. Pat. 6,453,190) and Schulz (U.S. Pat. 5,622,170), as set forth above, and further in view of Acker et al. (U.S. Pat. 6,618,612).

As to claim 76, Chader et al. in view of Acker et al. and Shultz is described above (i.e., claim 63) with respect to the smart instrument with wireless transceiver, computer system and sensor system with wireless transceiver. Chader et al. further discloses a patient tracker (24), which constitutes a smart instrument (col.5, lines 59-62, col.9, lines 30-37) connected to the patient by what looks like a band (Fig.1) to secure the reference markers (26) with respect to the patient. Since frame (24) is rigid, the reference markers (26) are immovable with respect to each other and since Chader et al. does not explicitly disclose what the band is or whether it is flexible, the band appears to only provide limited placement options on the body (e.g., head,

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chest, arm). However, Acker et al. ('612) discloses a similar¹ instrument tracking system in the same field of endeavor in which the reference markers (225, Fig.7) can be secured to the patient by a flexible sheet (220) (col.13, lines 30-39). Acker ('612) teach that use of moveable reference markers, including the combination with the flexible sheet, allows for placement of the markers at any desired location or orientation on the body (col.13, lines 33-39), prevents interference with surgeon access to the patient because of the lower profile (col.13, lines 40-43 and lines 51-54), and allows for placement closer to the field of interest (col.13, lines 54-56). Since both Chader et al. and Acker et al. teach systems in which markers are secured to the body, it would have been obvious to substitute one fastening means for another to achieve the predictable result of securing the markers to the body.

As to claim 77, it is noted that since the computer of Chader et al. can determine locations of the LEDs, determining such locations in 3D space on the flexible material, would inherently result in a contour. In addition, since Applicant's only structure for being "adapted to determine the contour of the smart instrument and perform a surface matching operation with a known contour" is a computer, the computer of Chader et al. is considered as being capable of performing such function. As to claim 78, since the flexible material can move and still be detected, it is considered a dynamic reference frame.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

¹ See col.2, line 62 to col.3, line 17.

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 74 and 75 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-26 of U.S. Patent No. 6,306,126 in view of Cosman (U.S. Pat. 6,675,040). Claims 15-26 of U.S. Pat. 6,306,126 encompass a calibration tool including a base, four columns, a plurality of IR LEDs and two slidable plates, each having an aperture. The patented claims fail to mention the structure of the surgery system in which it is intended to be used. Cosman disclose at least one smart instrument (282, Fig.6), a computer system (292), a sensor system (284) including a sensor array that has at least three linear infrared CCDs (286,288,290, col.13, lines 51-54) and at least one transceiver (304, col.14, lines 8-20). Cosman also teach the need for calibration of the instrument (col.5, lines 34-38, col.6, lines 57-60). It would have been obvious to one of ordinary skill in the art to have used the calibration tool of the patented claims in a infrared position sensing system as taught by Cosman so as to provide accurate calibration of the sensed tools.

Response to Arguments

11. Applicant's arguments filed October 6, 2009 have been fully considered but they are not persuasive.

The Examiner's acceptance of Applicant's Declaration filed under 37 CFR 1.132 filed October 6, 2009, coupled with Applicant's statement that the invention was subject to assignment to the same entity at the time the invention was made (note page 6 of the remarks filed October 6, 2009), establishes a common assignee between the instant application and the Moctezuma reference (U.S. Pat. 6,306,126). This has raised raises the issue of obvious-type double patenting since the differences between the structure covered in the Moctezuma claims and claims 74 and 75 appear to be in the instrument/sensor array, which has been shown to be obvious during prosecution of the instant application.

Regarding Applicant's arguments directed to claim 63, the Examiner will maintain the previous rejection of claim 68, which in has been re-written as claim 63. The Examiner takes the position that calling an instrument "unused" but active does not structurally distinguish over any other instrument (including "used" but active, or "unused" and un-active) and further takes the position that, when interrogating one instrument, the LEDs on a second instrument must be deactivated so as not to confuse the system as to the position of the first instrument. This would read on a temporary setting of the LEDs to zero, as broadly as claimed.

As to claim 76, the Examiner will maintain the previous rejection of this claim since the claim does not define the combination of flexible material and LEDs in a way so as to exclude any other structure which couples the LEDs to one side of the material (It is noted that the Examiner erroneously cited passages from Acker, U.S. Pat. 5,752,513 regarding the adhesive

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tape. This has been corrected in the rejection above.) . With that said, even if the claim is amended to specify that the flexible material is formed as a broad, thin continuous surface with the LEDs directly disposed on/in said surface, the Examiner has anticipated this with the use of Acker, (U.S. Pat. 6,618,612) which teaches the use of a flexible sheet with attached reference markers.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P. Leubecker/
Primary Examiner
Art Unit 3739

jpl